



Global Access to NIH Vaccine Technologies

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Vaccine Research at the NIH

- Primary Areas: HIV, Influenza, Rotavirus, Dengue, PIV and RSV, Ebola, HPV, Bacterial Diseases
- Basic Research
 - Live attenuated
 - Recombinant
 - DNA and vectored vaccines
 - Protein based vaccines
 - Virus Like Particles (VLP)
 - Conjugate vaccines (bacterial polysaccharides)
 - Adjuvants
- Clinical trials
- Pilot plant and GMP manufacturing facility off site



NIH Office of Technology Transfer (OTT)

- Patenting and Licensing of NIH inventions
 - 6000 scientists in the intramural program
 - 3500 US Patents, 1000's biological materials
- 1400 active licenses: 85% non-exclusive and 80% US
- 25 FDA approved products to date with 52 products currently in clinical trials





NIH Product Licensing Principles

- Technology based on request and need of recipient institution/company
- Granting only the appropriate scope of rights
- Reserve nonexclusive rights for research
- Preference for non- or partial exclusivity
- Enforceable milestones and benchmarks
- Maximize development of products for the public health
- Ensure appropriate return on public investment





Vaccine Technologies with Global Health Significance - Strategy

- Regional approach taking into consideration the needs of OECD AND Emerging and LDC markets
- Outside OECD Countries, preference for local/regional vaccine manufacturing organizations
 - More rapid market entry and uptake in developing countries
 - Driven by local public health and business needs
- Consider filing for patent protection in countries where vaccines will be produced and licensing unpatented biological materials





Licensing of Vaccines with Global Health Significance - Strategy

- Possible support by NIH during development period
 - Consultation
 - Biological materials
 - Clinical trial collaboration
 - Collaborative R&D Agreements (CRADAs)
- Licensing technologies to global NGOs (PATH, IVI, IAVI, AERAS) to partner with regional vaccine producers
- US and European Licensees
 - Mechanisms for distribution in developing countries: directly, requirements for sublicensing, or by limiting the geographic scope of each license



Success To Date

Licensed Technologies :

Dengue, Typhoid, Meningococcal,
Rotavirus, Hepatitis A, HPV and Varicella-
Zoster Vaccine Technologies

To Institutions in:

Brazil

Mexico

China

Nigeria

Egypt

South Africa

India

Vietnam

Korea (for SE Asia)

WHO and PATH (for Africa)



Dengue Vaccine

Live Attenuated Tetravalent 1-4 vaccine

Licensees:

- Biological E – India
 - Panacea – India
 - Butantan – Brazil
 - Vabiotech - Vietnam
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- NIH and Butantan of Brazil are working closely with PDVI (Pediatric Dengue Vaccine Initiative) to move forward with clinical trials.
 - Technology is also being currently evaluated by several Pharmaceutical companies
 - Licensees received seed viruses and other biological materials to support the development of the vaccine

NIH Licensees for Human-Bovine Reassortant Rotavirus Vaccine Technology

■ India

- Shantha Biotechnics Pvt. Ltd.
- Bharat Biologicals International Ltd.
- Biological E Ltd.
- Serum Institute of India Ltd. (SII)

■ China

- Wuhan Institute for Biological Products
- Sinovac Biotech Ltd.
- Xinkexian (Beijing) Biological Technology Co., Ltd.

■ Brazil and Latin America

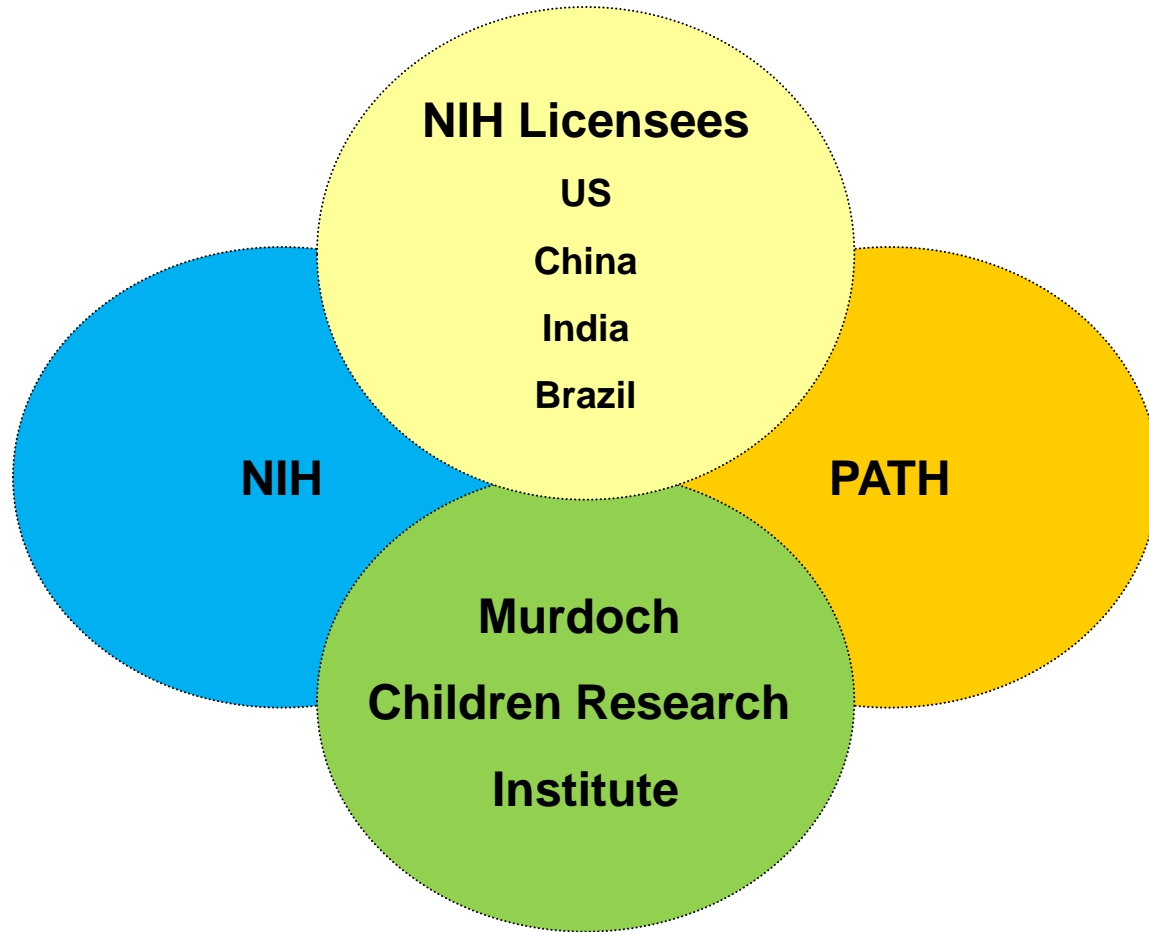
- Fundação Butantan

■ North American and Europe - Aridis Pharmaceuticals

Exclusive North America, EU, Brazil. Non-exclusive elsewhere



The Partnership for Global Development Rotavirus Vaccine





Influenza Vaccines at the NIH

Information about **clinical studies** for all vaccines including influenza vaccines at the NIH can be found at: <http://intramural.nih.gov/index.tml>

General information about worldwide clinical studies as tracked by the US Government: <http://clinicaltrials.gov/>

Influenza vaccines: 796 worldwide clinical studies; 29 conducted at the NIH

Licensing
OPPORTUNITIES

NIH Technologies Available for Licensing

www.ott.nih.gov/Technologies/AbsSearchBox.aspx

Featured Influenza Technologies www.ott.nih.gov/ft



NIH: Partners For Global Public Health

NIH www.nih.gov

Technology Transfer

www.ott.nih.gov

Neglected Diseases
Technologies Available

www.ott.nih.gov/nd

